MAY 2 1 2014

510(k) Summary: SILC™ Fixation System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Christina Kichula
Group Manager, Regulatory Affairs

Date Prepared: November 12, 2013

Device Name: SILC™ Fixation System

Classification: Per 21 CFR as follows:
§888.3010 Bone Fixation Cerclage, Sublaminar
Product Codes OWI
Regulatory Class II, Panel Code 87

Predicate(s): Zimmer Spine Universal Clamp Spinal Fixation System, K060009, K110348
Medicrea LigaPASS, K112736
Pioneer Songer Cable System, K922952

Purpose:
The purpose of this submission is to request clearance of the SILC™ Fixation System.

DEVICE DESCRIPTION:
The SILC™ Fixation System consists of bands, clamps that mate with 4.5mm-6.5mm diameter rods, and associated manual surgical instruments. Bands are manufactured from polyethylene terephthalate (PET) with commercially pure titanium tips per ASTM F67, and clamps are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F138, F1295, F1472, and F1537. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium molybdenum alloy implants.

INDICATIONS FOR USE:
The SILC™ Fixation System consists of temporary implants for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular

scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions.

The SILC™ Fixation System may also be used in conjunction with other medical implants made of similar metals whenever "wiring" may help secure the attachment of other implants.

Performance Data:
Mechanical testing (static band tension, static and dynamic band pull-through, static axial grip, and static torsion grip) was conducted in accordance with ASTM F1798 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices.

Conclusions / Basis of Substantial Equivalence:
The SILC™ Fixation System implants are similar to the predicate implants with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. The SILC™ Fixation System performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Globus Medical, Incorporated
Ms. Christina Kichula
Group Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K133482
Trade/Device Name: SILC™ Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 21, 2014
Received: April 22, 2014

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K133482

Device Name: SILC™ Fixation System

INDICATIONS:

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Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

James P. Bertram -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133482